

PATENT COOPERATION TREATY

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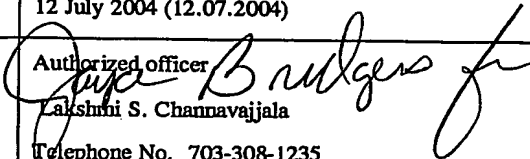
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 22 JUL 2004

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Applicant's or agent's file reference 00786/425WO2		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/12496	International filing date (day/month/year) 23 April 2003 (23.04.2003)	Priority date (day/month/year) 29 April 2002 (29.04.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/36 and US Cl.: 424/464, 195.1, 468			
Applicant THE GENERAL HOSPITAL CORPORATION			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>14</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 15 October 2003 (15.10.2003)		Date of completion of this report 12 July 2004 (12.07.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer  Lakshmi S. Channavajjala Telephone No. 703-308-1235	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/12496

I. Basis of the report**1. With regard to the elements of the international application: ***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-15 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages 16-20 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the drawings:
pages none _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/12496

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 4-10, 14-20 AND 24-30

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 4-10, 14-20 AND 24-30

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/12496**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)

Claims NONE

YES

Claims 1-3, 11-13 AND 21-23

NO

Inventive Step (IS)

Claims NONE

YES

Claims 1-3, 11-13 AND 21-23

NO

Industrial Applicability (IA)

Claims 1-3, 11-13 AND 21-23

YES

Claims NONE

NO

2. CITATIONS AND EXPLANATIONS

Claims 1-3, 11-13 and 21-23 lacks novelty under PCT Article 33(2) as being anticipated by US 6,277,398 to Caruso ('398).

'398 teach an analgesic composition comprising a capsaicinoid such as capsaicin together with a compound such as dextromethorphan or dextorphan. '398 teach that capsaicin can be combined with several opioid analgesics such as morphine; codeine etc. '398 teaches the composition for treating pain. '398 do teach capsaicin as vanilloid receptor agonist. However, the property is inherent to capsaicin because the capsaicin is also recited by instant disclosure as a vanilloid receptor.

Claims 1-3, 11-13 and 21-23 lacks an inventive step under PCT Article 33(3) as being obvious over 5,688,825 to Makriyannis et al ('825) in view of US 6,277,398 to Caruso ('398).

'825 teach a pharmaceutical composition for reducing pain in an individual comprising administering anandamide amidase. '895 teach anandamide as a natural agonist, exhibiting activity comparable to cannabinoids (col. 1). '895 do not teach using anandamide directly or anandamide together with a therapeutic compound.

'398 teach an analgesic composition comprising a capsaicinoid such as capsaicin together with a compound such as dextromethorphan or dextorphan. '398 teach that capsaicin can be combined with several opioid analgesics such as morphine, codeine etc. '398 teaches the composition for treating pain. Therefore, it would have been obvious for a skilled artisan to use any of the known compounds such as cannabinoids, capsaicin or anandamide etc., together with therapeutic agents because the cannabinoids, capsaicin or anandamide etc. exhibit analgesic activity when administered and thus help relief the pain.

Claims 1-3, 11-13 and 21-23 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

NONE